56056

BASF Corporation

Certified Mail 7001 1940 0000 1633 0874

Return Receipt Requested

BASF

8EHQ-0202-15087

January 15, 2002

Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention & Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Contain NO CBI

Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) – Interim Results of a prenatal developmental toxicity study in Wistar rats with Imidazol (CAS-No. 288-32-4) conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany

BASF Corporation is submitting interim results of a prenatal developmental toxicity study in Wistar rats (strain CrlGlxBrlHan:WI) with Imidazol. The test substance was administered as an aqueous solution by gavage to 25 mated female rats/group at doses of 0, 20, 60 and 180 mg/kg body weight on day 6 through day 19 post coitus. The study was carried out in accordance with the following guidelines: OECD Guidelines for Testing of Chemicals, Guideline 414 and EPA, Health Effects Test Guidelines; OPPTS 870.3700.

Relevant Results:

The following observations were made in the dams of the high dose group (180 mg/kg bw): salivation after treatment in 6/25 dams and vaginal hemorrhage in 1/25 dams. At this dose level, the compound did not influence food consumption and body weight gain; furthermore, no compound related macroscopic findings in the dams were recorded.

Cesarean section revealed a markedly increased postimplantation loss (43.4%, mainly late resorptions), a significantly decreased mean litter size as well as increased placental weights in these dams. In addition to significantly decreased fetal weights, signs of developmental toxicity were found at the high dose level (180 mg/kg bw) during external examination, including a statistically significant increase in the number of litters (6/21), number of fetuses (12/132) and percentage of fetuses per litter with malformations (anasarca and cleft palate). Thus the effects were observed at maternally toxic doses. There were no findings noted at 60 and 20 mg/kg bw.

Although these findings occurred only at high dose levels, which are far above any expected human exposure, BASF Corporation understands that the reporting of the study results is in accordance with EPA's policy. Results from this study will be included on the appropriate Material Safety Data Sheets.

8EHQ-02-15087

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

mk

88020000073

1609 Biddle Avenue, Wyandotte, Michigan 48192 (313) 246-6100